DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 12, 2017

Rayence Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K171417
Trade/Device Name: 1417WGC_127μm and 1417WGC_140μm
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: May 1, 2017
Received: May 15, 2017

Dear Dave Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171417

Device Name

1417WGC_127um and 1417WGC_140um

Indications for Use *(Describe)*

1417WGC_127um and 1417WGC_140um are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: June 7, 2017

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Rayence Co., Ltd.
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Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name:	**:** 1417WGC_127μm and 1417WGC_140μm
Common Name	: Digital Flat Panel X-ray Detector
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Product Code	: MQB

Predicate Device :

Device	:1417WGA
510(k) Number	: K131114
Common Name	: Digital Flat Panel X-ray Detector
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Product Code	: MQB

Reference Device:

Device :	: 1417WGC (Manufactured by Rayence)
510(k) Number :	: K141563
Common Name	: Digital Flat Panel X-ray Detector
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Product Code	: MQB

2. Device Description

While 1417WGC_127μm digital X-ray detector is identical to 1417WGC (K141563), both 1417WGC_127μm and 1417WGC_140μm are wired/wireless digital solid state X-ray detectors which are based on flat-panel technology. The wireless LAN(IEEE 802.11a/g/n/ac) communication signals images captured to the system and improves the user operability through high-speed processing. This radiographic image detector and processing unit consists of a scintillator coupled to an a-Si TFT sensor. This device needs to be integrated with a radiographic imaging system. Both devices do not operate as an X-ray generator controller but both can be utilized to capture and digitalize X-ray images for radiographic diagnosis The RAW files can be further processed as DICOM compatible image files by separate console SW (K160579 / Xmaru View V1 and Xmaru PACS/ Rayence Co.,Ltd.) for a radiographic diagnosis and analysis.

3. Indication for use

1417WGC_127μm and 1417WGC_140μm are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

4. Summary of Design Control Risk management

1417WGC_127μm digital X-ray detector is identical to 1417WGC (K141563). 1417WGC_140μm digital X-ray detector is a modification of 1417WGA (K131114) was developed for the purpose of ideal for in-room and portable imaging with a film detector. 1417WGC_140μm is slightly thinner and lighter than 1417WGA.

The risks and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design change were successfully mitigated and accepted.

5. Summary of the technological characteristics of the device compared to the

predicate device:

1417WGC_127μm digital X-ray detector is identical to 1417WGC (K141563). 1417WGC_140μm detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, 1417WGA.

5.1 Comparison table

Characteristic	**Proposed** **Rayence Co.,Ltd.** 1417WGC		**Predicate** **Rayence Co.,Ltd.** 1417WGA		
Feature					
510(k) number			K131114		
Intended Use	1417WGC_127μm and 1417WGC_140μm are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.		1417WGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.		Same
Detector Type	Amorphous Silicon, TFT		Amorphous Silicon, TFT		Same
Scintillator	1417WGC_127μm 1417WGC_140μm	Gd2O2S:Tb	1417WGA	Gd_2O_2S:Tb	Same
Imaging Area	14 x 17 inches		14 x 17 inches		Same
Pixel matrix	127 : 3328 X 2816 140 : 3052 X 2500		3328 x 2816		Similar
Pixel pitch	127 μm / 140 μm		127 μm		Similar
Resolution	3.9 lp/mm		3.9 lp/mm		Same
A/D conversion	14 bit for 127 μm /16 bit for 140 μm		14 bit		Same
Preview time	≤2(wied / wireless)		2~3 seconds (wired) / 3~5 seconds (wireless)		Similar
Data output	RAW *The RAW files are convertible into DICOM 3.0 by console S/W		RAW *The RAW files are convertible into DICOM 3.0 by console S/W		Same
Dimensions	460 × 384 × 15 mm		460 × 417 × 15.9 mm		Similar
Weight	3.0 kg (incl. battery)		3.9 kg (incl. battery)		Similar
Application	General Radiology system or Wireless/Wired portable system		Wireless portable system Available with upright stand, table,		Same

	Available with upright stand, table, universal stand.	universal stand	
Added Optional Components	Battery & Battery Charger Interface Box IrDA module	Battery & Battery Charger	Similar

5.2 Scintillator layer

**scintillator* layer. (* *scintillator : a phosphor that produces scintillations*)

	Proposed	**Predicate**
Gd_2O_2S:Tb (Gadolinium Oxysulfide)	1417WGC_127μm 1417WGC_140μm	1417WGA

5.3 Added Optional Components (Comparison with Predicate device)

Components	**Description**
Battery & Battery Charger 	Sources of electricity.
Mobile Battery Charger 	
Interface Box 	1) Connector to synchronize the detector and generator. 2) Data transfer and charging battery while detector is in use (Connect between detector and Interface Box), Up to three detector can be connected. 3) Transmitting an image/command between the detector and PC. 4) Wireless AP.
IrDA module 	Sharing function for PC and detector.

5.4 Recommended Generator Specifications

Model	Manufacture	Specification			
CMP 200	Communications & Power Industries		32kW	40kW	50kW
		kVp	40-125		40-150
		mA	10-400	10-500	10-630
EDITOR HFe 501	Rontgenwerk Bochum	kVp	40-150		
		mA	10-630		
UD150L-40E/40F	Shimadzu	kVp	40-150		
		mA	@100 kVp- 500(320)		
			@80 kVp- 630(400)		
PXR-321B	Poskom Co.,Ltd.	kVp	125/150		

6. Summary of Performance Testing

1417WGC_127µm digital X-ray detector is identical to 1417WGC (K141563). 1417WGC_140µm Digital Flat Panel X-Ray Detectors have the same indications for use, the same imaging area (14 x 17), based on the same scintillator material (Gd2O2S:Tb), the same resolution (3.9 lp/mm), performance, and safety characteristics compared to the predicate devices. The pixel matrix and pixel pitch sizes are different but the differences do not raise new concerns for the safety and effectiveness of the subject device.

The non-clinical test report and clinical consideration report for each subject device were prepared and submitted to FDA separately to demonstrate the substantial equivalency of the subject devices compared to each respective predicate device. The non-clinical test report contains the MTF, DQE and NPS test results of 1417WGC_140µm by using the identical test equipment and same analysis method described by IEC 62220-1.

The comparative result of the MTF and DQE test for 1417WGC_140µm detector with respect to the predicate device demonstrated that the MTF and DQE of the both 1417WGA performed similarly compared with the predicate devices. The MTF and DQE represents the ability to visualize object details of a certain size and contrast. 1417WGC_140µm has similar MTF and DQE performance at all spartial frequencies, especially from 2 lp/mm to 3.5 lp/mm. The comparison of the MTF and DQE for 1417WGC_140µm detector demonstrated that the performed almost same with 1417WGA.

To further demonstrate the substantial equivalency of two devices, clinical images are taken from both

subject devices and reviewed by a licensed US radiologist to render an expert opinion. Both the test subject (1417WGC_140μm) and the predicate devices (1417WGA) have been evaluated and compared by taking sample radiographs of similar age groups and anatomical structures in accordance with the test protocol of diagnostic radiography evaluation procedure.

After a broad review of plain radiographic images taken with the 1417WGC_140μm and 1417WGA, the images obtained with the 1417WGC_140μm are superior to the same view obtained from a similar patient with 1417WGA, the predicate devices. In general, both the spatial and soft tissue contrast resolution are superior using the 1417WGC_140μm. Specifically, the soft tissues on extremity were seen with better clarity. There is little difficulty in evaluating a wide range of anatomic structures necessary to provide a correct conclusion.

Based on the non-clinical and clinical consideration test and the outcome of a comparative review by an expert for both devices, the sponsor can claim the substantial equivalency between the subject devices and their predicate devices in terms of diagnostic image quality.

The manufacturing facility is in conformance with the design control procedure requirements and the relevant EPRC standards as specified in 21 CFR 802.30 and the records are available for review.

7. Summary for any testing in the submission:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (Medical electrical equipment Part 1:General requirements for basic safety and essential performance) was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2: 2007.
Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
All test results were satisfactory.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Rayence Co., Ltd. concludes that 1417WGC_127μm and 1417WGC_140μm are safe and effective and substantially equivalent in comparison with the predicate device.